

**Background note on the relationship between
MDCG 2020-6
and
MEDDEV 2.7/1 rev. 4 on clinical evaluation**

MDCG 2020-6 document *Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC - A guide for manufacturers and notified bodies*, references in Appendix I the sections of [MEDDEV 2.7/1 rev. 4](#) which are still relevant under the MDR for the application of the MDCG 2020-6.

For your convenience MEDDEV 2.7/1 rev. 4 is embedded below



2_7_1_rev4_en.pdf